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Apparatus for monitoring load bearing rehabilitation exercises of a transfemoral amputee fitted with an osseointegrated fixation: a proof-of-concept study

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ABSTRACT

The purpose of this proof-of-concept study was to determine the relevance of direct measurements to monitor the load applied on the osseointegrated fixation of transfemoral amputees during static load bearing exercises. The objectives were (A) to introduce an apparatus using a three-dimensional load transducer, (B) to present a range of derived information relevant to clinicians, (C) to report on the outcomes of a pilot study and (D) to compare the measurements from the transducer with those from the current method using a weighing scale. One transfemoral amputee fitted with an osseointegrated implant was asked to apply 10 kg, 20 kg, 40 kg and 80 kg on the fixation, using self-monitoring with the weighing scale. The loading was directly measured with a portable kinetic system including a six-channel transducer, external interface circuitry and a laptop. As the load prescribed increased from 10 kg to 80 kg, the forces and moments applied on and around the antero-posterior axis increased by 4 fold anteriorly and 14 fold medially, respectively. The forces and moments applied on and around the medio-lateral axis increased by 9 fold laterally and 16 fold from anterior to posterior, respectively. The long axis of the fixation was overloaded and underloaded in 17 % and 83 % of the trials, respectively, by up to ± 10 %. This proof-of-concept study presents an apparatus that can be used by clinicians facing the challenge of improving basic knowledge on osseointegration, for the design of equipment for load bearing exercises and for rehabilitation programs.

Keywords:

Rehabilitation; lower limb amputation; osseointegration; load bearing; force sensor

1. Introduction

1.1 Osseointegrated fixation: solution for transfemoral amputation

Over the last ten years, a few groups have developed an innovative surgical method of attachment of the prosthesis for transfemoral amputees that is based on direct skeletal anchorage. In this case, the socket is replaced by an osseointegrated fixation including metallic parts implanted in the residual femur which become integrated with the bone [1-3]. One of the most used fixations includes an implant, an abutment and a retaining bolt [4, 5]. So far, this technique, experienced by over 100 transfemoral amputees worldwide, has proved to be a successful alternative for amputees who experience complications in using a conventional socket-type prosthesis due to a short residual limb and soft tissue problems [6]. The absence of a prosthetic socket can alleviate the skin problems and residual limb pain. This technique has contributed to a significant improvement in the quality of life of transfemoral amputees [7, 8].

1.2 Rehabilitation: static load bearing exercises

Currently, osseointegration in lower limb amputation requires two stages of surgery [4, 5, 9]. First, the implant is inserted into the shaft of the femur (Stage I). The implant develops a firm biological bonding with the bone, named osseointegration, over a period of six months [10, 11]. Then, the abutment is connected to the implant, penetrating through the skin, to allow attachment of the external prosthesis (Stage II).

After the second surgery, the amputees have to undergo an extensive rehabilitation program including, but not limited to, static load bearing exercises (LBE). They are based on the principle that a timely application of a suitable amount of stress stimulates osseointegration and prepares the bone to tolerate the forces and moments likely to be incurred during daily living [12]. These exercises involve applying a load twice a day for several minutes. The prescribed load increases incrementally by a maximum of 10 kg per week until full standing weight can be borne safely and comfortably without bothersome pain. In most cases, this is achieved approximately three months after the

Stage II surgery but it may take longer depending on body weight, the pain level experienced by the patient and the quality of the residual skeleton [9, 12, 13]. Applying suitable stress during this period is critical. Overloading might place the bone-implant interface at risk while underloading might extend unnecessarily the already long rehabilitation program. Following this stage, the rehabilitation program continues through dynamic LBE (e.g., walking between parallel bars, with two crutches, one crutch, a stick, etc).

1.3 Monitoring of load bearing exercises

Monitoring the forces and moments during the LBE is essential to make sure that the load prescribed is applied consistently as required. Currently, this monitoring is conducted using a weighing scale. Affordable, low-tech and easy-to-use, this device has the flexibility required by the patients to perform the exercises daily in the environment of their choice (e.g., home, work, etc). The scale is mainly used to provide a practical indicator of the load to be applied [9, 13]. Unfortunately, this method presents a number of shortcomings due to the lack of precision, control, knowledge and recollection of the actual forces and moments. For instance, the scale provides instantaneous feedback to the patient only on the magnitude of the vertical component of the applied force. This corresponds to the force applied on the long axis of the fixation if the femur is perpendicular to the ground. The moment around the long axis of the fixation when the femur is perpendicular to the ground is not assessed and neither are the components of force and moment generated along and around the other two axes when the fixation is not perpendicular to the ground.

In a gait laboratory, these components can be calculated using inverse dynamic equations [14-16]. This method relies on kinematic data captured by a motion analysis system and the ground reaction forces measured by force-plates. Unfortunately, this experimental setting is incompatible with the practical constraints of the daily routine.

Thus, clinicians currently have limited means to gather accurately the actual amount of stress depending on magnitude and the duration of the load applied on the fixation.

1.4 Portable kinetic system

In principle, the load applied could be monitored using load sensors embedded into the prosthesis. Homemade transducers can be used but they could pose problems of calibration, reliability and accuracy [17-21]. More recently, portable kinetic systems based on a low profile commercial load cell connected to a recording device have been introduced [22-25]. Previous studies using this method have examined the magnitude and variability of load applied on the residuum of transfemoral amputees fitted with a socket and on the osseointegrated fixation during walking with and without aids in the laboratory, and during activities of daily living [24-27]. This method presents the distinct advantages of being portable and able to measure directly the three components of force and moment without calculations.

Consequently, this method seems to be a relevant and practical solution to monitor static LBE, as it has the potential to provide real-time feedback to the patients and to record data for the clinicians. However, there is currently limited work demonstrating the relevance of this system.

1.5 Purpose and objectives

The purpose of this proof-of-concept study was to determine the relevance of a method based on direct measurement to monitor the load applied on osseointegrated fixation during static LBE. The objectives were (A) to introduce an apparatus using a three-dimensional load transducer, (B) to present a range of derived information relevant to clinicians, (C) to report on the outcomes of a pilot study and (D) to compare the measurements from the transducer with those from a weighing scale.

2. Methods

2.1 Participant

One male (46 yr, 1.82 m, 96.1 kg / 942.74 N) was asked to participate. He was fully rehabilitated like most participants in previous studies focusing on walking aids [27]. This enabled a single recording session of all the loading conditions with the same fitting of the transducer.

The research institution's human ethics committee approved this study. The participant provided informed written consent.

2.2 Apparatus

The loading was directly measured with a kinetic recording system including a six-channel transducer, external interface circuitry and a laptop all connected via serial cables. The output of the transducer was recorded digitally and stored onto the laptop at a sampling frequency of 200 Hz using a customized LabView program (National Instruments, Austin, TX). The same commercial transducer (Model 45E15A; JR3 Inc, Woodland, CA) presented previously was used [22, 23]. It was constructed from a solid billet of aluminium measuring 11.43 cm in diameter, 3.81 cm thick and weighing less than 800 g. Its internal componentry consisted of strain gauges, amplifiers and signal conditioning circuitry. Its maximum capacity was 2,273 N for the long (L) axis, 1,136 N for the antero-posterior (AP) and medio-lateral (ML) axes, and 130 N.m for moments about the three axes. Accuracy was 0.1 % of the maximum capacity. The transducer was mounted to plates that were positioned between the long pylon and the adaptor, a 5.5 cm high piece of aluminium designed to fit the abutment on one side and a standard prosthetic pyramidal adaptor on the other (Figure 1). The transducer was aligned in a way that its coordinate system was co-axial with the long axis of the abutment and the two other axes were mutually orthogonal. One of these axes corresponded to the antero-posterior direction (anterior was positive) and the other with the medio-lateral direction (lateral was positive).

The load prescribed was monitored using a weighing

scale placed on the ground. A frame (70 cm x 40 cm) with two armrests was used to maintain balance and to ensure his safety.

*** Insert Figure 1 here ***

2.3 Procedure

The participant was asked to apply 10 kg (98.10 N), 20 kg (196.20 N), 40 kg (392.40 N) and 80 kg (784.80 N), representing 10.41 %, 20.81 %, 41.62 % and 83.25 % of his body weight (BW) respectively, for a set period, via self-monitoring of the scale. The participant performed three trials of each load prescribed. He was free to adjust his position and to rest between trials if needed. The recording was triggered and stopped approximately two seconds before and five seconds after the loading, respectively (Figure 1).

The procedure replicated the static LBE as conducted during the rehabilitation [9, 13], except the loading duration was shorter to avoid fatigue.

2.4 Data analysis

The raw data generated by the transducer was pre-processed and analysed using a customized Matlab software program (Math Works Inc, Natick, MA). Firstly, raw force and moment data were adjusted using a specific recording of an initial unloaded condition to remove any offset in the data and a transducer specific calibration matrix provided by the manufacturer to eliminate sensor cross-talk. Secondly, the relevant segment of data to analyse was selected. This corresponded to the period when force along the long axis (F_L) was relatively stable after the beginning of the loading on the scale (Figure 1). Thirdly, the resultant of the forces and moments was calculated. Fourthly, the loading during the selected stable segment was characterised by several derived parameters that can be used as clinical indicators, including:

- The mean and standard deviation of the resultants and three components of the forces and moments. These are simple indicators of the overall magnitude and the distribution of the loading over time.
- The slope of the linear regression line through the loading data corresponding to difference of loading divided by duration. This indicator reflects the consistency over time of the load applied. The weak slope indicates that the linear regression line is flat and therefore that the load applied was the same over time, as required in the rehabilitation program.
- The impulse was used as clinical indicator providing a single value of overall amount of stress taking into consideration the magnitude and the duration of the load applied [28].

Finally, the differences between the forces applied on the long axis (F_L) and the resultant (F_R), and load prescribed (L_P) were determined, so that a positive difference indicated that the force applied was higher than the load prescribed. This enabled the comparison of the measurements from the transducer with those from the weighing scale.

3. Results

An example of loading profile for forces and moments applied on the abutment when the load prescribed (L_P) was 20 kg is presented in Figure 1.

The mean and one standard deviation of the forces and moments for all the trials are plotted in Figure 2. As the load prescribed increased from 10 kg to 80 kg, the forces and moments applied on and around the antero-posterior axis increased by 4 fold anteriorly and 14 fold medially, respectively. The forces and moments applied on and around the medio-lateral axis increased by 9 fold laterally and 16 fold from anterior (i.e., 10 kg, 20 kg) to posterior (i.e., 40 kg, 80 kg), respectively.

*** Insert Figure 2 here ***

The trial-by-trial characterisation of forces and moments applied on the abutment for the four loads prescribed are provided in Table 1. The slope of each component was going down (negative) and up (positive) in 27% (13) and 73% (35) of the forces, and 10% (5) and 90% (45) of the moments, respectively. The magnitude of the negative and positive slopes of the components ranged from 0 to 0.50 for the forces and from 0.37 to 7.35 for the moments. The value of impulse varied because of the differences in magnitude of the loading and duration of the relevant data set.

*** Insert Table 1 here ***

The comparison between the load prescribed (L_P) and the forces applied on the long axis (F_L) and the resultant (F_R) is presented in Table 2. A positive and negative values indicated that the force measured was larger (overloaded) and smaller (underloaded) than load prescribed, respectively. The fixation was overloaded 17 % (2) and 25 % (3) of the trials by 5.64 ± 4.95 % and 4.72 ± 4.69 % of the long axis force and the resultant, respectively. However, the fixation was underloaded 83 % (10) and 75 % (9) of the trials by 4.03 ± 2.21 % and 5.90 ± 4.23 % of the long axis force and the resultant, respectively.

*** Insert Table 2 here ***

4. Discussion

4.1 Characterisation of loading

As expected, the force applied on the long axis was the largest in all conditions. Surprisingly, the moments around the medio-lateral axis were large in the posterior direction, particularly for the 40 kg and 80 kg loading, compared to the ones reported in previous studies focusing on walking [24, 25]. This might be because the participant had to bend his trunk forward to see the dial on the scale. The range of slopes indicated that the load was applied inconsistently over time although the LBE measured was supposed to be static.

The results revealed some variability within the trial. The participant tended to increase the weight on the scale during the trial, giving the number of slopes going up. It

might help to reach a more comfortable position. The variability within a loading condition was low for all the loads prescribed. This indicated that the participant used the same loading technique and kept his body position consistent for a given loading condition. This might be due to the fact that the participant was familiar with the LBE. The differences between loading conditions, particularly on the medio-lateral and antero-posterior axes confirmed previous visual observations reporting that the patients gradually increased the weight on the scale by shifting their body weight sideways and forward [12].

A difference of up to $\pm 10\%$ between the forces applied and load prescribed could be considered as acceptable. It validated the current monitoring method to a certain extent. However, in principle, the repeated underloading of the fixation during the course of the static LBE might put the bone-implant interface at risk and create potential complications as the strength of osseointegration might be insufficient to handle the subsequent dynamic LBE.

4.2 Relevance of proposed apparatus

This proof-of-concept study indicated that the proposed apparatus consisting of a commercial transducer, a laptop and a customized software package were effective in monitoring the load applied on the osseointegrated fixation during LBE.

The compact dimensions and fitting arrangements of the transducer were suitable for a portable kinetic system that can be used in clinical settings and, more importantly, in the patient's own environment. The measurement capacity of the transducer (e.g., six-channel, maximum loading, accuracy, etc) was sufficient to determine the three components of the true forces and moments during the load bearing exercises as actually conducted during rehabilitation. This insight into the forces and moments related to the medio-lateral and antero-posterior axes in particular, was critical since the results demonstrated that the limb was not only pressed axially onto the scale resulting in off-axis loading. A laptop facilitated the recording and storage of the information using a customized program. Furthermore, subsequent customized analysis enabled the characterisation of the loading by looking at the variations of the magnitude of the forces and moments (i.e., mean and standard deviation, and slope) as well as the overall quantity of the loading (i.e., impulse).

This study highlighted the difficulty of achieving appropriate loading through feedback from the vertical axis only. The magnitude of the off-axis loads and moments indicated that it is important to control these loads in order to stimulate safely the bone-implant interface, particularly in the early stages of the osseointegration process.

4.3 Developments of future prototype

This proof-of-concept study has provided sufficient technical information to further develop a fully functioning prototype of an apparatus specifically designed for clinical applications. Improving the patient-apparatus interface will be required. For instance, a range of combinations of audio, tactile and/or visual and real-time feedback would allow the

participant to monitor the application of the load and, consequently, readjust the loading to be on target if needed [29]. The results of this study demonstrated that a sampling frequency of 60 Hz will be sufficient considering the variation of the signal within a trial. All these features could be easily implemented using a handheld computer, for example.

4.4 Tool for clinical studies

The implementation of a three-dimensional transducer system as presented here will enable the patient to apply only the prescribed loads. This will facilitate the longitudinal studies of LBE during the course of rehabilitation for a cohort of participants. This will provide a better understanding of the inter-participant differences in loading profile. Kinematic and dynamic measurements were outside the scope of this proof-of-concept study. However, their combination will establish the link between loading profile and loading technique (e.g., body position).

Both longitudinal and cross-sectional studies can help to build a broader perspective on the LBE. This will be essential to improve basic knowledge on osseointegration, the design of equipment for LBE and to refine rehabilitation programs in the areas of the loading techniques, loading progression and loading requirement on and around the medio-lateral and antero-posterior axes in particular [30]. All combined, this should result in shorter and safer static LBE.

5. Conclusions

A portable system based on a commercial transducer has been presented that enables the monitoring of the load applied on the residuum of transfemoral amputees fitted with an osseointegrated fixation during static load bearing exercises. An example of raw results and some of the derived information were provided for one transfemoral amputee to illustrate the capacities of this new apparatus.

This proof-of-concept study highlighted the shortcomings of the current use of a weighing scale due to the lack of monitoring of off-axis loading. This study established that the core technology of the proposed apparatus overcame this shortcoming while offering the flexibility and accuracy required to know, to control and to monitor the load during static load bearing exercise within the constraints of a rehabilitation program.

In conclusion, the apparatus presented here is a stepping-stone in the development of on-board and user-friendly sensors to be used by clinicians facing the challenge of safely enhancing the osseointegration of lower limb prostheses for amputees.

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LIST OF FIGURE AND TABLES

Figure 1. Measurement of loading including a six-channel transducer (A) mounted between plates (B) connected to an adaptor (C) and the abutment of the osseointegrated fixation (D), and a long pylon (E), a frame (G), and a weighing scale (F). Example of loading profile and segment of data to analyse for forces (F) and moments (M) applied on and around the medio-lateral (ML), antero-posterior (AP) and long (L) axes of the abutment when the load prescribed (L_P) applied on the scale was 20 kg (196.20 N).

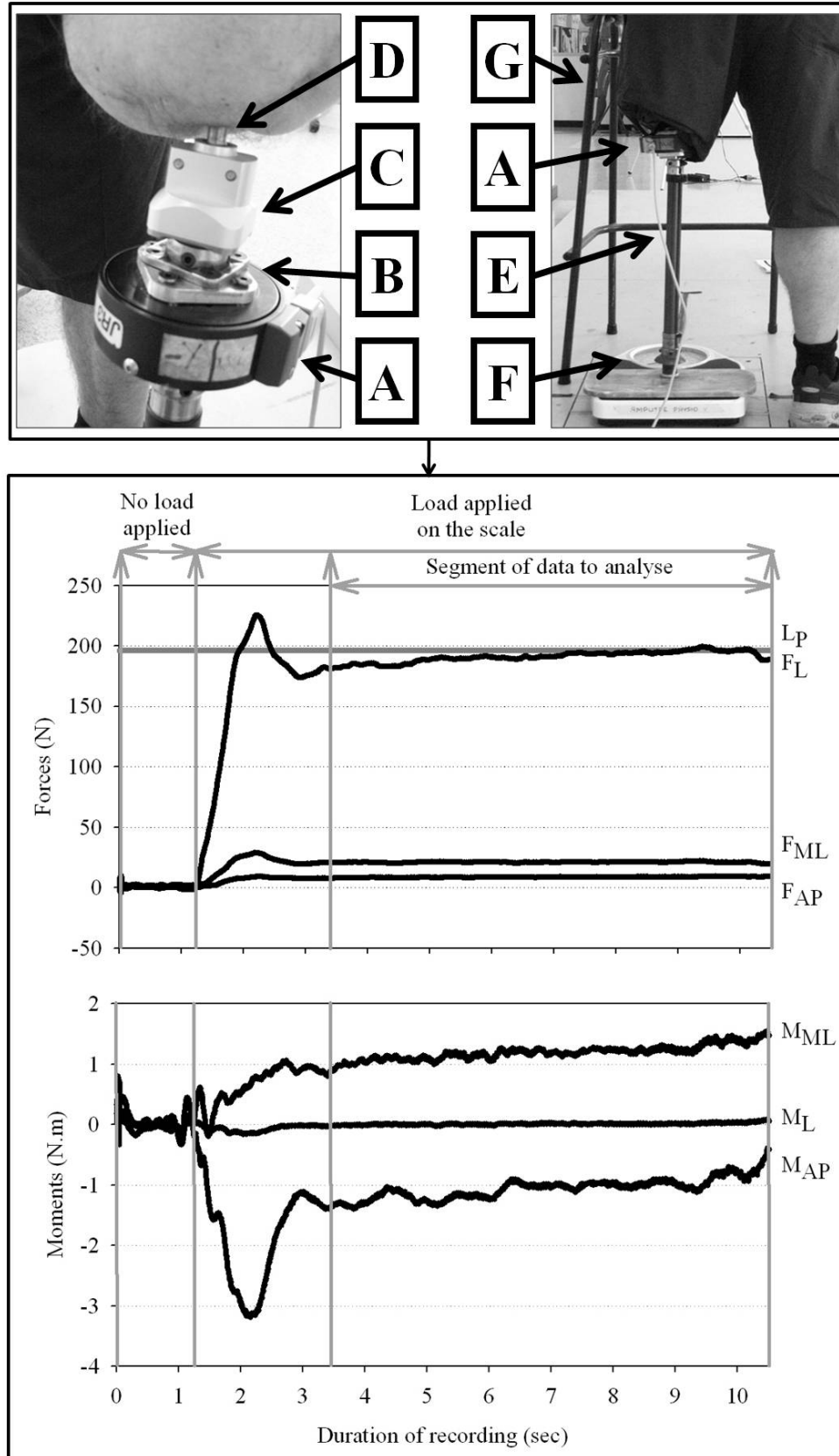


Figure 2. Overall mean and one standard deviation of forces (F) and moments (M) applied on and around medio-lateral (ML), antero-posterior (AP) and long (L) axes, and the resultant (R) for the three trials in each load prescribed.

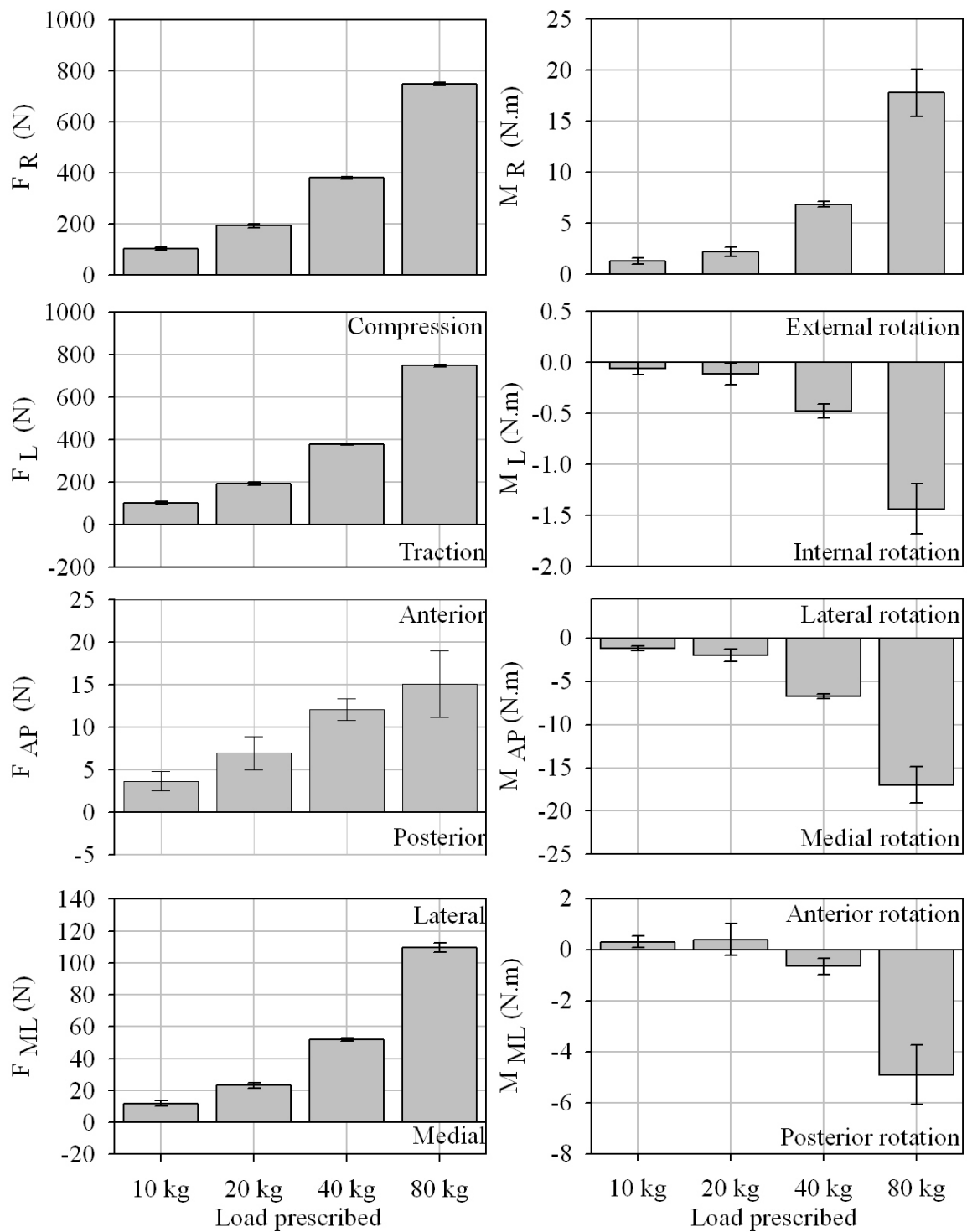


Table 1: Characterisation of forces and moments applied on the abutment for load prescribed of 10 kg (98.10 N), 20 kg (196.20 N), 40 kg (392.40 N) and 80 kg (784.80 N).

Trial	10 kg ⁽¹⁾				20 kg ⁽²⁾				40 kg ⁽³⁾				80 kg ⁽⁴⁾			
	Mean (N)	SD (N)	Slope	Impulse (N.sec)	Mean (N)	SD (N)	Slope	Impulse (N.sec)	Mean (N)	SD (N)	Slope	Impulse (N.sec)	Mean (N)	SD (N)	Slope	Impulse (N.sec)
Forces																
Resultant																
1	107.94	4.53	0.29	594.20	197.35	4.68	0.28	1185.08	378.80	3.28	0.23	2464.05	749.52	3.19	0.02	4500.91
2	100.99	3.16	0.25	505.46	194.46	3.52	0.30	973.23	378.55	3.33	0.24	2273.18	740.04	2.63	-0.01	1853.81
3	97.02	4.90	0.24	485.58	184.57	2.43	-0.17	923.81	382.06	2.87	-0.04	2294.27	752.20	3.66	0.01	2636.48
Long axis																
1	107.07	4.53	0.29	589.38	195.67	4.65	0.28	1174.98	375.01	3.25	0.24	2439.42	740.99	3.15	0.03	4449.65
2	100.21	3.15	0.26	501.51	193.08	3.50	0.30	966.36	374.76	3.30	0.25	2250.40	732.23	2.57	0.00	1834.24
3	96.36	4.86	0.24	482.27	183.01	2.40	-0.17	915.97	378.35	2.83	-0.03	2272.01	744.18	3.58	0.02	2608.39
Antero-posterior axis																
1	4.18	0.94	0.34	71.39	7.16	1.16	0.33	148.06	12.42	1.34	0.11	337.83	16.26	1.26	-0.24	670.16
2	3.67	1.01	0.19	59.77	8.85	1.31	0.07	106.28	11.93	1.20	-0.01	312.71	19.87	1.41	-0.22	263.94
3	3.17	1.17	0.50	53.77	4.97	1.26	-0.36	117.25	11.89	1.24	-0.27	310.56	9.87	1.46	-0.28	382.21
Medio-lateral axis																
1	12.97	1.37	-0.12	23.01	24.66	1.12	0.19	43.00	51.93	1.02	0.06	80.81	111.60	1.36	-0.10	97.68
2	11.94	1.23	0.05	18.36	21.24	0.98	0.18	44.28	52.08	1.04	0.14	71.63	105.36	1.40	0.24	49.77
3	10.74	1.23	0.13	15.85	23.43	0.96	0.10	24.88	51.72	1.13	0.14	71.43	109.04	1.59	0.35	34.58
Moments																
Resultant																
1	1.53	0.19	-1.09		2.40	0.24	-1.92		6.84	0.26	-0.74		20.04	0.42	-1.20	
2	1.23	0.20	-0.75		1.62	0.21	-0.46		6.77	0.24	-2.34		15.23	0.37	-0.96	
3	1.00	0.22	1.10		2.55	0.26	-2.29		6.86	0.27	-2.20		15.68	0.56	-1.22	
Long axis																
1	-0.06	0.06	-3.77		-0.14	0.06	2.24		-0.44	0.07	0.78		-1.66	0.07	0.99	
2	-0.06	0.06	2.48		0.01	0.06	2.63		-0.51	0.06	1.98		-1.29	0.05	1.27	
3	-0.06	0.06	-3.01		-0.20	0.06	4.17		-0.49	0.06	3.53		-1.15	0.08	7.35	
Antero-posterior axis																
1	-1.48	0.18	-1.72		-2.37	0.25	1.19		-6.82	0.26	2.90		-19.03	0.44	-1.84	
2	-1.16	0.20	0.82		-1.03	0.26	2.37		-6.69	0.24	2.04		-14.70	0.39	1.16	
3	-0.94	0.23	0.37		-2.52	0.26	2.45		-6.78	0.27	2.48		-15.15	0.51	1.65	
Medio-lateral axis																
1	0.31	0.25	0.56		0.24	0.18	1.89		-0.31	0.21	0.63		-6.03	0.25	1.34	
2	0.32	0.21	1.00		1.22	0.20	2.15		-0.88	0.19	2.16		-3.75	0.29	0.72	
3	0.26	0.20	-1.02		-0.26	0.19	2.16		-0.83	0.21	2.10		-3.84	0.48	1.16	

⁽¹⁾ Trial 1 = 5.5 sec, trial 2 = 5.0 sec, trial 3 = 5.0 sec

⁽²⁾ Trial 1 = 6.0 sec, trial 2 = 5.0 sec, trial 3 = 5.0 sec

⁽³⁾ Trial 1 = 6.5 sec, trial 2 = 6.0 sec, trial 3 = 6.0 sec

⁽⁴⁾ Trial 1 = 6.0 sec, trial 2 = 2.5 sec, trial 3 = 3.5 sec

Table 2: Differences between load prescribed (L_P) and the forces applied on the long axis (F_L) and the resultant (F_R).

Trial	$F_L - L_P$		$F_R - L_P$	
	(N)	(%)	(N)	(%)
10 kg				
1	8.97	9.14	9.84	10.03
2	2.11	2.15	2.89	2.95
3	-1.74	-1.77	-1.08	-1.10
20 kg				
1	-0.53	-0.27	1.15	1.18
2	-3.12	-1.59	-1.74	-1.78
3	-13.19	-6.72	-11.63	-11.85
40 kg				
1	-17.39	-4.43	-13.60	-3.47
2	-17.64	-4.50	-13.85	-3.53
3	-14.05	-3.58	-10.34	-2.64
80 kg				
1	-43.81	-5.58	-35.28	-8.99
2	-52.57	-6.70	-44.76	-11.41
3	-40.62	-5.18	-32.60	-8.31